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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,967	03/23/2007	Fabrizio Dolfi	293004US0X PCT	2319

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EXAMINER	
POCHAS, CHRISTOPHER MICHAEL	
ART UNIT	PAPER NUMBER
4121	

NOTIFICATION DATE	DELIVERY MODE
01/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,967	DOLFI ET AL.	
	Examiner	Art Unit	
	Christopher Pochas	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/18/2006, 11/07/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

1) Claims 12-25 are pending.

2) Priority is claimed to French application 04 01718 and PCT application PCT/FR05/00368. Claims 12-25 gain the benefit of these priority claims.

Non Final Rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over J. Immunol., 2000, 165: 1534-1540, in view of U.S. Patent 5744156.

Claims 12-14 Chloroquine was known in the art (J. Immunol., 2000, 165: 1534-1540), to inhibit interleukin 6 and it is well known in the art that IL-6 inhibitors are useful in the treatment of rosacea.

J. Immunol., 2000, 165: 1534-1540 does not teach ingredients besides an IL inhibitor which may be useful in the treatment of rosacea.

Claims 15-20 and 24 U.S. Patent 5744156 (hereafter 574) discloses the use of topical compositions with an IL inhibitor (metronidazole), as well as the other ingredients listed

in the pending claims that are useful for the treatment of rosacea in all its stages. Line 57 of column 5 of 574 reads, "Among these active agents, there may be mentioned by way of example:

antiseptics such as salicylic acid and its derivatives (n-octanoyl-5-salicylic acid), or crotamiton;

antibacterials such as clindamycin phosphate, erythromycin or antibiotics ofthe class of tetracyclines;

antiparasitic agents, in particular metronidazole or pyrethrinoids;

antifungal agents, in particular compounds belonging to the family of imidazols such as econazol, keoconazol or miconazol or their salts, polyene compounds, such as amphotericin B, compounds of the family of allyl amines, such as terbinafine, or alternatively octopirox;

steroidal anti-inflammatory agents such as hydrocortisone, betamethasone valerate or clobetasol propionate, or non-steroidal anti-inflammatory agents such as ibuprofen and its salts, diclofenac and its salts, acetylsalicylic acid, acetaminophen or glycyrrhetinic acid;

anesthetic agents such as lidocaine hydrochloride and its derivatives;

antipruritic agents such as thenaldine, trimeprazine or cyproheptadine;

anti-free radical agents such as alpha-tocopherol or its esters, superoxide dismutases, certain metal chelators or ascorbic acid and its esters;

keratolytic agents such as 13-cis- or all-trans-retinoic acid, benzoyl peroxide or hydroxy acids."

Claim 25 Furthermore, example 4 of 574 discloses a composition containing metronidazole and an antioxidant. 574 does not teach the specific IL inhibitors of the pending claims.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of 574 with the teachings of J. Immunol., 2000, 165: 1534-1540 to provide a rationale to use a method of treating rosacea consisting of topically applying the composition described in the pending claims because the ingredients of said composition are well known in the art to be useful in the treatment of rosacea.

Claims 21-23 As for the specific ranges disclosed in claims 21-23, section 2144.05 of the MPEP states, "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Furthermore, it is disclosed in J. Immunol., 2000, 165: 1534-1540 that a concentration of chloroqine on the order of at least 100 μM is needed to significantly inhibit IL-6 and therefore the concentrations of these pending claims is obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pochas whose telephone number is (571)270-7722. The examiner can normally be reached on Monday to Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMP

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121